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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/935,629	09/23/1997	E. ALAN BATES		8872

7590 12/31/2001

GARY HOFFMAN
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EXAMINER
ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
1743	27

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

MF=27

Office Action Summary	Application No.	Applicant(s)	
	08/935,629	Bates et al.	
	Examiner	Art Unit	
	LYLE A ALEXANDER	1743	

-- Th MAILING DATE of this communication appears on th cov r she t with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,23,24 and 37-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,23,24 and 37-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,8,23-34 and 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daffron et al. in view of Senior.

See the appropriate paragraph of paper 23.

Response to Arguments

Applicant's arguments filed 10/15/01 have been fully considered but they are not persuasive.

The Office will send out a corrected filing receipt. .The rejection over WO 97/33519 have been dropped in light of the corrected filing date .

Applicants state Dafforn teaches a recessed test strip that would not require shielding by a cap. The Office maintains sufficient motivation of record exists to isolate the area contacted by the sample with a cap.

Applicants state Senior teaches a structure which blocks an end rather than covering a well. Senior teaches a cover capable of also covering a well (see figures 1-2).

Applicants state the cover taught by Senior will not provide the claimed positive sealing. Senior teaches in column 2 lines 33+ the cap seals to prevent gross loss of moisture.

Applicants state Senior teaches the cap in a sliding relationship and not the claimed snap fit. Dafforn et al. teaches in column 13 "snap fit" relationships are well known in the art and sufficient motivation of record exists to use the snap fit design.

Applicants state the features of claim 40 are not taught by the art of record. Dafforn et al. teach in column 13 lines 33+ use of a "dropper,syringe needle or the like" which has been read on the claimed "pipette".

Applicants request the Office to supply a reference teaching photocopying is notoriously well known in the art. Any dictionary will furnish a definition of photocopying as reproducing or copying a results.

The Declaration filed under 37 CFR 1.132 filed 10/15/01 is insufficient to overcome the rejection of claims 1,8 and 23-45 are based upon Dafforn et al. and Senior as set forth in the last Office action because:

The Declaration has been fully considered. It appears the Declaration is attempting to demonstrate commercial success. The court has decided *Ex parte Standish*, 10 USPQ2d 1454,1458 (Bd. Pat. App. & Inter. 1988) that language of "constructed according to the disclosure of the claims of [the] patent application" or other equivalent language dose not establish a nexus between the claimed invention and the commercial success because there is not evidence that the product or process which has been sold corresponds to the claimed invention , or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. The present Declaration states "merits of the invention" which has been

read as equivalent to "constructed according to the disclosure of the claims of [the] patent application" or other equivalent language.

Additionally, applicants must show that the claimed features were responsible for the commercial success. In *ex parte* proceedings before the Patent and Trademark Office, an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of nonobviousness is to be accorded substantial weight. See *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996) (Inventor's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention.). Merely showing that there was commercial success of an article which embodied the invention is not sufficient. *Ex parte Remark*, 15 USPQ2d 1498, 1502-02 (Bd. Pat. App. & Inter. 1990). Compare *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988) (In civil litigation, a patentee does not have to prove that the commercial success is not due to other factors. "A requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence.").

See also *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985) (commercial success may have been attributable to extensive advertising and position as a market leader before the introduction of the patented product); *In re Fielder*, 471 F.2d 690, 176 USPQ 300 (CCPA 1973) (success of invention could be due to recent changes in related technology or consumer demand; here success of claimed voting ballot could be due to the contemporary drive toward greater use of automated data processing techniques); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 225 USPQ 20 (Fed. Cir. 1985) (evidence of licensing is a secondary consideration which must be carefully appraised as to its evidentiary value because licensing programs may succeed for reasons unrelated to the unobviousness of the product or process, e.g., license is mutually beneficial or less expensive than defending infringement suits); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (Evidence of commercial success supported a conclusion of nonobviousness of claims to an immunometric "sandwich" assay with monoclonal antibodies. Patentee"s assays became a market leader with 25% of the market within a few years. Evidence of advertising did not show absence of a nexus between commercial success and the merits of the claimed invention because spending 25-35% of sales on marketing was not inordinate (mature companies spent 17-32% of sales in this market), and advertising served primarily to make industry aware of the product because this is not kind of merchandise that can be sold by advertising hyperbole.).

To be pertinent to the issue of nonobviousness, the commercial success of devices falling within the claims of the patent must flow from the functions and advantages disclosed or inherent in the description in the specification. Furthermore, the success of an embodiment within the claims may not be attributable to improvements or modifications made by others. *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 224 USPQ 617 (Fed. Cir. 1985).

Gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A ALEXANDER whose telephone number is 703-308-3893. The examiner can normally be reached on MONDAY,WEDNESDAY,FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

LYLE A. ALEXANDER
PRIMARY EXAMINER

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December 21, 2001~~extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action~~.